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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,785	10/27/2003	Egisto Boschetti	9676-314-999	1038
20583	7590	01/24/2008		
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			EXAMINER JONES, DAMERON LEVEST	
			ART UNIT 1618	PAPER NUMBER
			MAIL DATE 01/24/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/692,785	Applicant(s) BOSCHETTI, EGISTO	
	Examiner D. L. Jones	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-11,15-21,56-60 and 63-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-11,15-21,56-60 and 63-68 is/are rejected.
- 7) ☒ Claim(s) 69-71 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/21/07</u> | 6) <input type="checkbox"/> Other: _____ |

ACKNOWLEDGEMENTS

1. The Examiner acknowledges receipt of the amendment filed 10/31/07 wherein the specification was amended and claims 1, 63, and 65 were amended, claims 2, 3, 12-14, 22-55, 61, and 62 were canceled, and claims 69-71 were added. In addition, the Examiner acknowledges the request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/31/07 has been entered.

Note: Claims 1, 4-11, 15-21, 56-60, and 63-71 are pending.

RESPONSE TO APPLICANT'S ARGUMENTS/AMENDMENTS

2. The Applicant's arguments and/or amendment filed 10/31/07 to the rejection of the claims made by the Examiner under 35 USC 103 have been fully considered and deemed non-persuasive for reasons of record in the office action mailed 7/12/07 and those set forth below.

I. The rejection of claims 1, 4-6, 11, 15-18, and 56-60 under 35 USC 103(a) as being unpatentable over Bachtsi et al (J. Microencapsulation, 1995, Vol. 12, No. 1, pp. 23-25) in view of Figge et al (US Patent No. 6,242,512) is MAINTAINED for reasons of record in the office action mailed 7/12/07 and those set forth below.

II. The rejection of claims 1, 4, 5, 8-11, 15-17, 19-21, 56-60, and 63-68 under 35 USC 103(a) as being unpatentable over Bachtsi et al (J. Microencapsulation, 1995,

Vol. 12, No. 1, pp. 23-25) in view of Tarara et al (US Patent No. 6,565,885) in further view of Figge et al (US Patent No. 6,242,512) is MAINTAINED for reasons of record in the office action mailed 7/12/07 and those set forth below.

III. The rejection of claims 1, 4-6, 11, 15-18, 56-60, 63-68 under 35 USC 103(a) as being unpatentable over Bachtisi et al (J. Microencapsulation, 1995, Vol. 12, No. 1, pp. 23-25) in view of Tarara et al (US Patent No. 6,565,885) in further view of Figge et al (US Patent No. 6,242,512) is MAINTAINED for reasons of record in the office action mailed 7/12/07 and those set forth below.

IV. The rejection of claims 1, 4-11, 15-21, 56-60, and 63-68 under 35 USC 103(a) as being unpatentable over Boschetti et al (US Patent No. 5,635,215) in view of Tarara et al (US Patent No. 6,565,885) in further view of Figge et al (US Patent No. 6,242,512) is MAINTAINED for reasons of record in the office action mailed 7/12/07 and those set forth below.

In summary, Applicant makes the following assertions, (1) the Examiner may be misunderstanding the rationale for Bachtisi's use of NaOH since the reference discloses that the NaOH was added to remove any unreacted chemicals. (2) Applicant asserts that the Figge added NaOH for a reason other than that being claimed by Applicant. (3) Applicant asserts that both Bachtisi and Figge are in non-analogous fields. (4) Applicant asserts that Bachtisi and Boschetti both in view of Tarara does not render obvious the microspheres of the instant invention since the content of the reference would not provide reason one to combine the teachings of the references to obtain the instant invention. (5) Applicant asserts that some of the cited prior art references do not

specifically state that the particles are sterile. (6) Applicant asserts that Boschetti discloses a different PVA from those of the instant invention. Specifically, the PVA used as polymers in Boschetti were irregularly shaped and not spherical.

Note that all rejections have been modified to include Figge et al (US Patent No. 6,242,512) and Kusano et al (US Patent No. 5,114,577). A detailed summary of each is provided below. However, what each document illustrates is that it is well known in the art to have a polyvinyl alcohol and sodium hydroxide composition. While neither of the cited documents specifically state that the NaOH neutralizes the aldehydes as in the instant invention, a skilled practitioner in the art would recognize that the combination is the same combination present in the instant invention and must have the same properties/functions as the composition of the instant invention. Applicant has repeatedly stated that since the references do not **explicitly state** that the NaOH is used for the same purpose as in the instant invention, then the reference cannot be prior art against the instant invention. The Examiner respectfully disagrees and once again states that while the prior art does not disclose Applicant's rational for adding a component; it is the same component that is used by Applicant. If a compound is inseparable from its properties, then the same compound, regardless of whether stated by the prior art or not, would have the same properties when combined with polyvinyl alcohol as in the instant invention. Thus, the skilled artisan would recognize that the actions that one component performs in the composition would be the same in both compositions. Hence, it is unclear how and why Applicant's NaOH which is added to neutralize the aldehydes of the polyvinyl alcohol are different from the NaOH added to

the polyvinyl alcohol of the prior art, regardless of the purpose for which the art adds the NaOH.

In regards to the references not stating that the microspheres are sterile, it should be noted that first, the rejections are combination rejections. Secondly, if for example, Bachtisi et al disclose that crosslink PVA particles have been used as carriers and delivery devices for enzymes, the skilled artisan would be motivated to use sterile particles since administering non-sterile particle could have negative effects on the subject. Thus, the skilled artisan would recognize the intended use of the microspheres being sterile and used in processes that require that the microspheres be sterile is obvious since the claimed invention and that of the art both require the same components and the art discloses the particles use for biological purposes. Hence, the instant invention like the prior art are both capable as being used in environments that require sterile particles. Also, Boschetti et al disclose that their microspheres are used for therapeutic embolization. Thus, the skilled practitioner would recognize that the if microspheres are being administered to a subject for therapeutic purposes, then the microspheres would be sterile since the administering of non-sterile microspheres would result in negative effects to the subjects. Thus, while the reference does not specifically state that the microspheres are sterile, such quality would be inherent. Likewise, the microparticles of Tarara et al were used for pharmaceutical purposes. Thus, once again, a skilled artisan would recognize that it is sterile, not non-sterile, microspheres being administered to a subject. Furthermore, it is noted that Boschetti et al disclose

that their microspheres are injectable and are used for therapeutic vascular occlusions (see abstract; column 3, lines 41-50).

In regards to the microspheres of Boschetti being irregular, a skilled artisan would recognize that while the overall composition may have some irregular shaped microspheres, the chance that every single microsphere is irregular is unlikely. Thus, the skilled artisan would recognize that the overall composition/mixture would have some spherical microspheres.

Figge et al disclose redispersible polymer powder based compositions (see entire document, especially, abstract). Possible polymers that maybe used are vinyl chloride copolymers (see entire document, especially, abstract; column 2, lines 64-67; column 3, lines 32-34). Figge et al disclose that in one of the preferred embodiments that the composition also comprises a neutralizing agent such NaOH, KOH, and $\text{Ca}(\text{OH})_2$ (column 5, lines 24-31; and column 6, lines 36-47).

Kusano et al disclose polymer compositions that may be crosslinked using dialdehydes such as glutaldehyde as used in the instant invention (see entire document, especially, abstract; column 5, lines 9-18; column 5, lines 55-62). The composition may comprise crosslinked polyvinyl alcohol (column 9, lines 5-21, especially, lines 20-21). The crosslinking reaction when carried out may also include sodium hydroxide (column 11, lines 58-65; column 13, lines 48-53). In Examples 8-11 and Table 8 (columns 22-24) disclose various combinations of polyvinyl alcohol and NaOH.

Furthermore, if all of the references encompass polyvinyl alcohol in combination

with NaOH, then a skilled artisan would conclude that the references are within the same field of endeavor. Thus, the reference teachings are combinable.

Once again, it is noted that the composition/product of the prior art is the same/similar as that being claimed by Applicant. Although, the cited prior art does not disclose the particular use, the composition/product would be capable of having the same use as Applicant's inventions since a composition/product and its properties are inseparable. Thus, Applicant's composition/product, like the cited prior art, would be 'capable of' performing the same function. Furthermore, based on the teachings of the prior art, inherent properties of compounds, and parameters that would be obvious to a skilled practitioner in the art, the cited prior art rejections are deemed proper.

CLAIM OBJECTIONS

3. Claims 69-71 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The claims are distinguished over the prior art of record because the prior art neither anticipates nor renders obvious that the aldehydes on the microspheres are neutralized by an amino-containing agent.

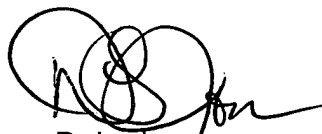
4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read 'D. L. Jones', with a stylized flourish at the end.

D. L. Jones
Primary Examiner
Art Unit 1618

January 17, 2008